

POTENCY REFERENCE SUBMISSION WORKSHEET

Establishment	
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A. CURRENT SUBMISSION			
1. Submission Date		2. Report ID	
3. Primary Product Code on Submission			
4. Purpose	<div style="display: flex; justify-content: space-between;"> Qualify new reference Extend dating Requalify existing reference </div>		
5. If qualifying new reference, indicate ID of reference being replaced			

B. POTENCY REFERENCE			
1. Identification/Lot No.		2. Storage Temperature	
3. Type of Reference	<div style="display: flex; justify-content: space-around;"> Master Working Serves as Both </div>		
4. Composition	<div style="display: flex; justify-content: space-between;"> <div> Matched Product Non-adjuvanted microbial harvest Other (describe)_____ </div> <div> Other Completed Product Purified antigen </div> </div>		
5. Protocol (select one)	<div style="display: flex; justify-content: space-between;"> Special Outline (ID_____) SAM (ID_____) </div> Other assay described in Section V Outline		
6. CVB Test Code		7. Working Dilution	
8. Additional products tested with this reference—other than code listed in part A.3 (Do not include combination packages.)			

C. HISTORY (if requalifying a reference or requesting extension of dating)	
1. Original reference approval date	
2. Current expiration date	

D. CVB USE ONLY	
1. Submission approved	_____Yes _____No
2. Approval date	
3. Assigned expiration date	
4. Comments	